



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,892	12/09/2003	Warren Douglas Sheffield	337348055US1	4677
25096	7590	12/19/2007		
PERKINS COIE LLP PATENT-SEA P.O. BOX 1247 SEATTLE, WA 98111-1247			EXAMINER REIDEL, JESSICA L	
			ART UNIT	PAPER NUMBER
			3766	
			MAIL DATE	DELIVERY MODE
			12/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/731,892	SHEFFIELD ET AL.	
	Examiner	Art Unit	
	Jessica L. Reidel	3766	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 05 November 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 05 November 2007. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ They raise the issue of new matter (see NOTE below);
- (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: 74 and 82.
- Claim(s) objected to: 13 and 48.
- Claim(s) rejected: 1, 4-7, 9-12, 14-23, 25-27, 32-43, 45-57, 61-70, 72, 73, 75, 76, 78-81 and 83-86.
- Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☒ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Kennedy J. Schaetzle/
Primary Examiner, AU 3766
December 17, 2007

Continuation of 3. NOTE:

Continuation of 11. does NOT place the application in condition for allowance because: Applicant's arguments are not found to be persuasive. In response to Applicant's argument that Schiff expressly teaches away from the elements of the Applicant's claims, the Examiner respectfully disagrees and believes that these issues were fully addressed in the previous Advisory Action of July 17, 2007 (herein the previous AA). In response to the new arguments presented, the Examiner maintains that Schiff is not limited to the use of deep brain electrodes since Schiff discloses at column 4, lines 66-67, that "a variety of electrodes can be employed for delivering the stimulation". Schiff further specifies at column 11, lines 29-32 that in addition to being applied to the patient's intralaminar nuclei, "the electrical stimulation can also extend to other regions of the brain". Although Schiff goes on to state at this portion of the reference, as cited by Applicant, that preferably, the electrical stimulation is applied to "only the patient's intralaminar nuclei without stimulating other regions of the patient's brain", a prior art reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). It appears that Schiff discloses at least two alternative embodiments, where one embodiment may be preferred over the other. The fact that one disclosed embodiment might be "preferred" over another disclosed embodiment does not constitute as evidence of a teaching away from the nonpreferred embodiment. Furthermore, the Examiner is unable to find throughout the Schiff reference, a portion that expressly teaches away from applying stimulation to other regions of the brain other than the intralaminar nuclei or any disclosure which discredits Schiff's own disclosed alternative embodiment of stimulating the intralaminar nuclei in combination with stimulating other regions of the brain. Notably, Schiff expressly describes a method "for improving coordination of function across a patient's cortical regions" in order to artificially induce a neural connection between two cortical regions not otherwise connected due to stroke or other neural injury. Schiff teaches that a plurality of the intralaminar subdivisions and projections thereof extend throughout multiple areas of the cortex and thalamus and Schiff expressly discloses that ~~that~~ one or a plurality of brain regions and/or subdivisions may be stimulated in either or both brain hemispheres, including cortical regions/areas (see Schiff column 7, lines 35-67, column 8, lines 1-57, column 11, lines 20-46, column 12, lines 29-51, column 13, lines 42-49, column 14, lines 2-67 and columns 15-20). Taken as a whole, the prior art of Schiff suggests to one having ordinary skill in the art that the cognitive function may be improved by stimulating the intralaminar nuclei alone or in combination with stimulating other regions of the brain and Schiff further suggests that through appropriate selection of which intralaminar nuclei to position electrodes adjacent, regions of the brain immediately proximate the selected location may be stimulated as well as regions remote from the selected location through interconnected intralaminar nuclei projections extending from the electrode position to those remote regions of the brain.

The Examiner has sufficiently reviewed Applicant's additional arguments that the Examiner's position in the previous AA was that cortical stimulation is an equivalent or substitute for deep brain stimulation (see page 19-22 of the Remarks), however, the Examiner respectfully disagrees that any argument of substituting one stimulation for the other was made by the Examiner. As discussed in the previous AA and in the Final Rejection of May 4, 2007 (herein the FR), Schiff discloses methods and systems for restoring impaired cognitive function in a patient by improving functional neural coordination across a patient's cortical regions through the use of deep brain stimulation electrodes and application of electrical signals to those deep-brain regions alone, or in combination with stimulation of other brain regions. Schiff discloses the essential features of the claimed invention except that it is not specified that the invention include stimulation electrodes positioned proximate the dura mater and outside a cortical surface. Both Firlik references disclose analogous yet improved methods and systems for restoring impaired cognitive function in a patient by electrically inducing/creating neural connections between neurons in various brain regions by electrically stimulating the cortex, deep brain regions or both the cortex and deep brain regions through the use and positioning of electrodes that are not deeply invasive and which allow for highly selective focused stimulation. As discussed in the previous AA and the FR, both Firlik references disclose various embodiments of stimulating cortical regions, stimulating deep-brain regions and of stimulating both cortical and deep-brain regions in combination where the electrode placement for any one of the three embodiments (i.e. cortical and/or deep brain stimulation) constitutes as an improvement over prior art methods, including those disclosed by Schiff and over other very invasive prior art methods/systems (see pages 2, paragraphs 13 of both Firlik references). The electrodes of Firlik '419 and Firlik '201, located proximate the dura mater and outside a cortical surface, accurately focus stimulation energy to a desired stimulation site, regardless of whether the site is selected as a cortical location, a deep-brain location or both, through the use of appropriate orientation control of the electrical energy supplied to the electrodes via a pulse system in a manner that is less-invasive and more effective than prior known methods. Firlik '419 and Firlik '201 both expressly disclose that the method and system, including electrodes and a stimulus apparatus positioned proximate the dura mater and outside a cortical surface offers an advantage over existing subcranial methods/systems that merely place electrodes proximate to a nerve portion because the method and system provides electrode configurations that generate an electrical field in a pattern designed for each specific stimulation site (see, for example, Firlik '419 Figs. 14-17, Abstract, page 1, paragraph 2, page 4, paragraphs 58-61, page 5, paragraphs 64-6, page 6, paragraph 73, pages 9-10, paragraphs 100 and 106 and pages 12-13, paragraphs 117-127). Therefore, since Schiff specifies that a variety of electrodes can be employed for delivering the electrical stimulation, that the electrical stimulation may extend to other regions of the brain in addition to the intralaminar nuclei and further that regions of the cortex may be selected for stimulation through intralaminar projections to those regions, it would have been obvious to one having ordinary skill in the art at the time the invention was to modify the Schiff such that the method and system includes the electrodes positioned as taught by Firlik '419 and Firlik '201 since such a modification would provide a means for highly selective deep brain stimulation or both highly selective deep-brain and highly selective cortical stimulation without inducing serious complications from overly invasive placement of electrodes into deep-brain regions. The proposed modification does not render the prior art unsatisfactory for its intended purpose – specifically, the modified Schiff reference is entirely capable of performing its intended purpose of restoring cognitive function through inducing the creation of neural pathways throughout different cortical regions through electrical stimulation of deep-brain regions or both deep-brain regions and cortical regions to thereby improve coordination of function across a patient's cortical regions.